: 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-Day Comment Request; NIH Information Collection Forms to Support Genomic Data Sharing for Research Purposes (OD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health Office of the Director (OD) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Julia Slutsman, Ph.D., Director, Genomic Data Sharing Policy Implementation Team, Office of Extramural Research, NIH, Office of Extramural Research, OD, NIH 6705 Rockledge Dr (RKL1), Room 800-C, Bethesda, MD 20892, or call non-toll-free number (301)-594-7783 or email your request including your address to: sharing@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance

of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information from those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: NIH Information Collection Forms to Support Genomic Data Sharing for Research Purposes - 0925-0670 - Expiration Date 11/31/2022 – REVISION - Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Sharing research data supports the National Institutes of Health (NIH) mission and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. NIH has longstanding policies to make a broad range of research data, including genomic data, publicly available in a timely manner from the research activities that it funds. Genomic research data sharing is an integral element of the NIH mission as it facilitates advances in our understanding of factors that influence health and disease, while also providing opportunities to accelerate research through the power of combining large and information-rich datasets. To promote robust sharing of human and non-human data from a wide range of large-scale genomic research and provide appropriate protections for research involving human data, the NIH issued the NIH Genomic Data Sharing Policy (NIH GDS Policy). Human genomic data submissions and controlled-access genomic and related phenotypic data are managed through the database of Genotypes and Phenotypes (dbGaP) which is administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH.

Under the NIH GDS Policy, all investigators who receive NIH funding to conduct large-scale genomic research are expected to register studies with human genomic data in Database of Genotypes and Phenotypes (dbGaP), no matter which NIH-designated data repository will ultimately maintain the data. As part of the study registration process, investigators must provide basic study information such as the type of data that will be submitted to dbGaP, a description of the study, and an institutional assurance (i.e., provided through submission of an Institutional Certification form) of the data submission which delineates any necessary limitations on the secondary use of the data (e.g., data cannot be shared with for-profit companies, data can be used only for research of particular diseases).

Investigators interested in using controlled-access data for secondary research must apply through dbGaP and be granted permission from the relevant NIH Data Access Committee(s). As part of the application process, investigators and their institutions must provide information such as a description of the proposed research use of controlled-access datasets that conforms to any data use limitations, agree to the Genomic Data User Code of Conduct, and agree to the terms of access through a Data Use Certification agreement. Requests to renew data access and reports to close out data use are similar to the initial data access request, requiring sign-off by both the requestor and the institution, but also ask for information about how the data have been used, and about publications, presentations, or intellectual property based on the research conducted with the accessed data as well as any data security issues or other data management incidents.

NIH has developed online forms, available through the Database of Genotypes and Phenotypes (dbGaP), in an effort to minimize burden for researchers and their institutional officials completing the study registration, data submission, data access, and renewal and closeout processes.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 72,301 hours.

Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Study Registration and Data Submission					
dbGaP Registration and Submission	Investigator Submitting Data	1,050	1	45/60	788
Institutional Certification	Investigator filling out Institutional Certification	1,050	1	45/60	788
Institutional Certification	Institutional Official to Certify Institutional Certification	1,050	1	30/60	525
Requesting Access to Data					
Data Access Request	Requester Submitting Request	3,900	10	45/60	29,250
Data Access Request	Institutional Signing Official to Certify Request	3,900	10	30/60	19,500
Project Renewal or Project Close-out					

Project Renewal or Project Close-out form	Requester Submitting Request	3,900	10	15/60	9,750
Project Renewal or Project Close-out form	Institutional Signing Official to Certify Request	3,900	10	18/60	11,700
Total		18,750	159,150		72,301

Dated: September 15, 2022.

Tara A. Schwetz,

Acting Principal Deputy Director,

National Institutes of Health.

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